Complete Summary

GUIDELINE TITLE

Ovarian cysts in postmenopausal women.

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Ovarian cysts in postmenopausal women. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2003 Oct. 8 p. (Guideline; no. 34). [36 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Ovarian cysts

GUIDELINE CATEGORY

Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine

Obstetrics and Gynecology
Oncology

INTENDED USERS

Nurses
Physicians

GUIDELINE OBJECTIVE(S)

To provide information, based on clinical evidence where available, on the investigation and management of postmenopausal women with known ovarian cysts.

TARGET POPULATION

Postmenopausal women with ovarian cysts

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment

1. Serum CA_{125} levels
2. Transvaginal and transabdominal ultrasound
3. Risk assessment and triage using "risk of malignancy index"
4. Histological assessment of excised tissue

Management

1. Conservative management (monitoring and follow up at appropriate time interval)
2. Surgical management
    - Laparoscopic oophorectomy
    - Laparotomy with full staging procedures
    - Cytology: ascites or washings
    - Clear documentation
    - Biopsies from adhesions and suspicious areas
    - Total abdominal hysterectomy (TAH), bilateral salpingo-oophorectomy (BSO), and infra-colic omentectomy
3. Patient counselling
4. Rapid referral to a cancer centre (for those women who are found to have an ovarian malignancy)

Aspiration of ovarian cyst fluid was considered but not recommended.

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Risk of malignancy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A search of Medline, Embase from 1966 to 2001 and of the Cochrane Database of Systematic Reviews was conducted, looking for relevant randomised controlled trials, meta-analyses, other clinical trials, and systematic reviews. The databases were searched using the relevant Medical Subject Heading (MeSH) terms including all subheadings. This was combined with a key word search using "ovarian," "cyst," "neoplasm," "pelvic mass," and "adnexal mass."

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The recommendations were graded according to the level of evidence upon which they were based. The grading scheme used was based on a scheme formulated by the Clinical Outcomes Group of the National Health Service (NHS) Executive.

Grade A - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)

Grade B - Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendations (evidence levels IIa, IIb, III)

Grade C - Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Following discussion in the Guidelines and Audit Committee, each green-top guideline is formally peer reviewed. At the same time the draft guideline is published on the Royal College of Obstetricians and Gynaecologists (RCOG) website for further peer discussion before final publication.

The names of author(s) and nominated peer reviewers are included in the original guideline document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

Levels of evidence (Ia-IV) and grading of recommendations (A-C) are defined at the end of the "Major Recommendations" field.

Diagnosis and Assessment of Ovarian Cysts

B - It is recommended that ovarian cysts in postmenopausal women should be assessed using CA_{125} and transvaginal grey scale sonography. There is no routine role yet for Doppler, magnetic resonance imaging (MRI), computed tomography (CT), and positron emission tomography (PET).

In order to triage women, an estimate needs to be made as to the risk that the ovarian cyst is malignant. This needs to be done using tests that are easily available in routine gynaecological practice. At present, these tests are serum CA_{125} measurement and ultrasound. [Evidence level IIa]

Ovarian cysts should normally be assessed using transvaginal ultrasound, as this appears to provide more detail and hence offers greater sensitivity than the transabdominal method. Larger cysts may also need to be assessed transabdominally. [Evidence level IIa]

B - It is recommended that a "risk of malignancy index" should be used to select those women who require primary surgery in a cancer centre by a gynaecological oncologist.

An effective way of triaging women into those who are at low, moderate, or high risk of malignancy and who hence may be managed by a general gynaecologist, or in a cancer unit or cancer centre respectively, is to use a risk of malignancy index. There are three well-documented risk of malignancy indices and the table below gives an example of one of these. This guideline is directed at postmenopausal women and therefore all will be allocated the same score for menopausal status. [Evidence level IIa]

Calculating the Risk of Malignancy Index (RMI): These are modifications of the original RMI using modified scores
RMI = U x M x CA125 U = 0 (for ultrasound score of 0); U = 1 (for ultrasound score of 1); U = 3 (for ultrasound score of 2-5). Ultrasound scans are scored one point for each of the following characteristics: multilocular cyst; evidence of solid areas; evidence of metastases; presence of ascites; bilateral lesions. M = 3 for all postmenopausal women dealt with by this guideline

CA_{125} is serum CA_{125} measurement in u/mL

The best prognosis for women with ovarian cancer is offered if a laparotomy and full staging procedure is carried out by a trained gynaecological oncologist. This procedure is likely to be performed in a cancer centre. However, the large prevalence of ovarian cysts in the postmenopausal population and the increase in their diagnosis means that it would not be feasible for all women with ovarian cysts that require surgery, whether benign or malignant, to be referred to a cancer centre. Women need to be triaged, so that a gynaecological oncologist in a cancer centre operates on those at high risk of having ovarian cancer, a lead clinician in a cancer unit operates on those at moderate risk, while those at low risk may be operated on by a general gynaecologist or offered conservative management. The high specificity and sensitivity of the risk of malignancy indices discussed makes them an ideal and simple way of triaging women for this purpose (The table below gives an example of a reasonable protocol for triaging women using the risk of malignancy index, RMI).The three risk of malignancy indices produce similar results. Using a cut off point of 250, a sensitivity of 70% and specificity of 90% can be achieved. Thus the great majority of women with ovarian cancer will be dealt with by gynaecological oncologists in cancer centres, with only a small number of referrals of women with benign conditions. However, as most of the cysts will be benign, gynaecologists in units at more local level will perform the majority of surgery. [Evidence level IIa]

It should be appreciated, however, that no currently available tests are perfect, offering 100% specificity and sensitivity. Ultrasound often fails to differentiate between benign and malignant lesions, and serum CA_{125} levels, although raised in over 80% of ovarian cancers, is raised in only 50% of stage I cases. In addition, levels can be raised in many other malignancies and in benign conditions, including benign cysts and endometriosis. [Evidence level IIa]

Those women who are at low risk of malignancy also need to be triaged into those where the risk of malignancy is sufficiently low to allow conservative management, and those who still require intervention of some form.

An Example of a Protocol for Triaging Women using the Risk of Malignancy Index (RMI)			
Risk	RMI	Women (%)	Risk of cancer (%)
Low	<25	40	<3
Moderate	25-250	30	20
High	>250	30	75

Management of Ovarian Cysts

Conservative Management

B - Simple, unilateral, unilocular ovarian cysts, less than 5 cm in diameter, have a low risk of malignancy. It is recommended that, in the presence of a normal serum CA_{125} levels, they be managed conservatively.

It is reasonable to manage these cysts conservatively, with a follow-up ultrasound scan for cyst of 2-5 cm, a reasonable interval being four months. This, of course, depends on the views and symptoms of the woman and on the gynaecologist's clinical assessment [Evidence level IIa].

Surgical Management

Those women who do not fit the above criteria for conservative management should be offered surgical management in the most suitable location, and by the most suitable surgeon as determined by the risk of malignancy index. Initial surgical management that has been assessed includes aspiration of the cyst, laparoscopy, and laparotomy.

Aspiration

B - Aspiration is not recommended for the management of ovarian cysts in postmenopausal women.

Laparoscopy

C - It is recommended that a "risk of malignancy index" should be used to select women for laparoscopic surgery, to be undertaken by a suitably qualified surgeon.

The laparoscopic management of benign adnexal masses is well established. However, when managing ovarian cysts in postmenopausal women, it should be remembered that the main reason for operating is to exclude an ovarian malignancy. If an ovarian malignancy is present then the appropriate management in the postmenopausal woman is to perform a laparotomy and a total abdominal hysterectomy, bilateral salpingo-oophorectomy, and full staging procedure. The laparoscopic approach should therefore be reserved for those women who are not eligible for conservative management but still have a relatively low risk of malignancy. Women who are at high risk of malignancy, as calculated using the risk of malignancy index, are likely to need a laparotomy and full staging procedure as their primary surgery. A suitably experienced surgeon may operate laparoscopically on those women that fall below this cut-off point. [Evidence level IV]

C - It is recommended that laparoscopic management of ovarian cysts in postmenopausal women should involve oophorectomy (usually bilateral) rather than cystectomy.

In a postmenopausal woman, the appropriate laparoscopic treatment for an ovarian cyst, which is not suitable for conservative management, is oophorectomy, with removal of the ovary intact in a bag without cyst rupture into the peritoneal cavity. This is the case even when the risk of malignancy is low. In most cases this is likely to be a bilateral oophorectomy, but this will be determined by the wishes of the woman. [Evidence level IV]

Women at intermediate risk undergoing laparoscopic oophorectomy should be counselled preoperatively that a full staging laparotomy would be required if evidence of malignancy is revealed. [Evidence level IV]

C - If a malignancy is revealed during laparoscopy or subsequent histology, it is recommended that the woman is referred to a cancer centre for further management.

If an ovarian cancer is discovered at surgery or on histology, a subsequent full staging procedure is likely to be required. [Evidence level IV]

B - A rapid referral to a cancer centre is recommended for those women who are found to have an ovarian malignancy. Secondary surgery at a centre should be performed as quickly as feasible.

Laparotomy

All ovarian cysts that are suspicious of malignancy in a postmenopausal woman, as indicated by a high risk of malignancy index, clinical suspicion, or findings at laparoscopy are likely to require a full laparotomy and staging procedure. This should be performed by an appropriate surgeon, working as part of a multidisciplinary team in a cancer centre, through an extended midline incision, and should include:

- Cytology: ascites or washings
- Laparotomy with clear documentation
- Biopsies from adhesions and suspicious areas
- Total abdominal hysterectomy (TAH), bilateral salpingo-oophorectomy (BSO), and infra-colic omentectomy

The laparotomy and staging procedure may include bilateral selective pelvic and para-aortic lymphadenectomy.

<u>Summary and Suggested Management Protocol</u>

Low Risk: Less than 3% risk of cancer

- Management in a gynaecology unit
- Simple cysts less than 5 cm in diameter with a serum CA_{125} level of less than 30 may be managed conservatively.
- Conservative management should entail repeat ultrasound scans and serum CA_{125} measurement every four months for one year.
- If the cyst does not fit the above criteria or if the woman requests surgery then laparoscopic oophorectomy is acceptable.

Moderate Risk: Approximately 20% risk of cancer

- Management in a cancer unit
- Laparoscopic oophorectomy is acceptable in selected cases.
- If a malignancy is discovered, then a full staging procedure should be undertaken in a cancer centre.

High Risk: Greater than 75% risk of cancer

- Management in a cancer centre

- Full staging procedure as described above.

Definitions:

Grading of Recommendations

Grade A - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)

Grade B - Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendations (evidence levels IIa, IIb, III)

Grade C - Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

CLINICAL ALGORITHM(S)

A clinical algorithm entitled "Flowchart for the Management of Ovarian Cysts in Postmenopausal Women" is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of postmenopausal women with ovarian cysts, including rapid referral and treatment for those with an ovarian malignancy

POTENTIAL HARMS

Risk of false positive and false negative diagnostic test results

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Clinical guidelines are "systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions." Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No. 1: Guidance for the Development of Royal College of Obstetricians & Gynaecologists (RCOG) Green-top Guidelines.
- These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Ovarian cysts in postmenopausal women. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2003 Oct. 8 p. (Guideline; no. 34). [36 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Oct

GUIDELINE DEVELOPER(S)

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

Royal College of Obstetricians and Gynaecologists

GUIDELINE COMMITTEE

Guidelines and Audit Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Professor Deirdre J Murphy, MRCOG (Chair); Lizzy Dijeh (Secretary); Ms Toni Belfield, Consumers' Representative; Professor P R Braude, FRCOG, Chairman, Scientific Advisory Committee; Mrs C Dhillon, Head of Clinical Governance and Standards Dept.; Dr Martin Dougherty, A. Director NCC-WCH; Miss L M M Duley, FRCOG, Chairman, Patient Information Subgroup; Mr Alan S Evans, FRCOG; Dr Mehmet R Gazvani, MRCOG; Dr Rhona G Hughes, FRCOG; Mr Anthony J Kelly MRCOG; Dr Gwyneth Lewis, FRCOG, Department of Health; Dr Mary A C Macintosh, MRCOG, CEMACH; Dr Tahir A Mahmood, FRCOG; Mrs Caroline E Overton, MRCOG, Reproductive medicine; Dr David Parkin, FRCOG; Oncology; Ms Wendy Riches, NICE; Mr Mark C Slack, MRCOG, Urogynaecology; Mr Stephen A Walkinshaw, FRCOG, Maternal and Fetal Medicine; Dr Eleni Mavrides, Trainees Representative

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Guideline authors are required to complete a "declaration of interests" form.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

Print copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Bookshop, 27 Sussex Place, Regent's Park, London NW1 4RG; Telephone: +44 020 7772 6276; Fax, +44 020 7772 5991; e-mail: bookshop@rcog.org.uk. A listing and order form are available from the RCOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guidance for the development of RCOG green-top guidelines. Clinical Governance Advice No 1. 2000 Jan. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.
- Searching for evidence. Clinical Governance Advice No 3. 2001 Oct. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

Additionally, Audit Criteria are provided in section 7 of the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

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